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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,391	01/08/2002	Eiji Shiojiri	215409US0	9970
22850	7590	04/20/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,391

Applicant(s)

SHIOJIRI ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-19 are pending.

Applicants' amendment filed January 26, 2004 is acknowledged. Applicant's response has been fully considered. Claims 1-19 have been amended. Therefore, claims 1-19 are examined.

Objection Withdrawn

2. The previous objection of claims 1 and 10 is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 14 in the amendment filed January 26, 2004.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 5-7 and 12-15 under 35 U.S.C.112, first paragraph, is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 13 in the amendment filed January 26, 2004.
4. The previous rejection of claims 1-19 under 35 U.S.C.112, second paragraph, is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 13-14 in the amendment filed January 26, 2004.

Claim Rejections - 35 USC § 102

5. The previous rejection of claims 1, 2, 4, 8-11 and 16-19 under 35 U.S.C.102(b) as being anticipated by Matsueda *et al.* (U. S. Patent 4,548,926, October 1985), is withdrawn in view of applicant's response at page 10 in the amendment filed January 26, 2004.

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6. The previous rejection of claim 2 under 35 U.S.C.102(b) as being anticipated by Saika *et al.* (WO/95/12611), is withdrawn in view of applicant's response at pages 10-11 in the amendment filed January 26, 2004.

7. The previous rejection of claim 1, 2 and 4 under 35 U.S.C.102(b) as being anticipated by Etzkorn *et al.* (J. Am. Chem Soc. 116, 10412-10425 (1994)), is withdrawn in view of applicant's response at pages 13 in the amendment filed January 26, 2004.

Objection to New Matter Added to Specification

8. The amendment filed January 26, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The specification does not indicate the peptide of Ac-Nap-Arg-Tyr-OMe is excluded, however, claims 1-2 and 4-19 in the amendment recite the new matters (see also paragraph 9).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 2 and 4-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 1, 2 and 4-19 are directed to a dipeptide or tripeptide having a naphthyl group and represented by the Formula (I), which excludes the compound of Ac-Nap-Arg-Tyr-OMe; or, a melanocyte-stimulating hormone inhibitory composition, a whitening agent, an immunofunction controlling agent, an appetite controlling agent, or a cosmetic preparation, which comprises the peptide of Formula (I) excluding Ac-Nap-Arg-Tyr-OMe. The specification indicates some specific examples in the peptide of Formula (I), e.g., Ar is 1-naphthyl or 2-naphthyl; X² is an alkyl group having 1 to 6 carbons; R⁶ is NHY, where Y can be acetyl; R⁴ is an amino acid side chain, preferably side chain from basic amino acid; R⁷ is an amino acid side chain, preferably side chain from hydrophobic amino acid; and R⁹ can be a methyl group (pages 8-13), it does not describe the exclusion of the compound of Ac-Nap-Arg-Tyr-OMe, especially the basic side chain of Arg is a preferable group for R⁴, and the hydrophobic side chain of Tyr is a preferable group for R⁷. Furthermore, the most potent compound that inhibits melanocyte-stimulating hormone is D-2-Nal-Arg-LeuNH₂ (page 27 of the specification), which has high sequence homology to Ac-Nap-Arg-Tyr-OMe. The lack of basis on the exclusion of Ac-Nap-Arg-Tyr-OMe in the specification as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

In response to the rejection of claims 1, 2 and 4 under 35 U.S.C.102(b) as being anticipated by Etzkorn et al., applicants have amended the claim to exclude the compound of Ac-Nap-Arg-Tyr-OMe; and indicated that the specification clearly described the excluded compound among a list of alternative species represented by the genus of compounds of Formula (I), and that MPEP 2173.05(i) states "if alternative elements are positively recited in the

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specification, they may be explicitly excluded in the claims", thus the addition of this negative limitation or exclusionary proviso does not constitute "new matter". The response has been fully considered, however, the argument is not found persuasive because the specification does not describe the exclusion of this specific compound, nor provides any reasoning for the exclusion (see the section above). Furthermore, the excluded compound contains preferable groups of the peptide of formula (I), thus the exclusionary proviso does not have any basis in the original disclosure. Regarding MPEP 2173.05(i), it also states any negative limitation or exclusionary proviso "must have" basis in the original disclosure, besides the statement "if alternative elements are positively recited in the specification, they may be explicitly excluded in the claims". However, in the instant case, there is no basis for the exclusionary proviso in the specification as indicated in the section above, thus the exclusionary proviso constitutes "new matter".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "X² Absent" in line 9 from the bottom of the claim. There is insufficient antecedent basis for this limitation in the claim because X² is defined as a single bond or a straight-chain or branched-chain alkylene group having 1 to 6 carbon atoms. Claims

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2-19 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 4, 8-11 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Saika *et al.* (WO/95/12611).

Saika *et al.* teach an endothelin receptor antagonist having the structure of formula (I), e.g., N-(2-naphthoyl)-N-methyl-D-phenylalanyl-L-tryptophan, which meets the structural criteria of the peptide of formula (I), where Ar is 2-naphthyl, n is 0, Ar-C(=O) is 2-naphthoyl, R² is methyl, R³ is H, R⁴ is D-phenylalanyl side chain, X² is single bond, X³ is NR¹⁰, R¹⁰ is H, m is 1, R⁷ is L-tryptophan side chain, R⁸ is H, X⁴ is O, and R⁹ is H (Example 21, page 50; claim 1). This compound can be formulated with a pharmaceutically acceptable carrier or diluent (page 39, paragraphs 3 and 4), which meet the criteria of claims 4, 8-11 and 16-19, because this compound has the same structure as a peptide of formula (I) of the claimed invention, thus it would be expected to have melanocyte-stimulating hormone inhibitory activity. Furthermore, the reference indicates the compound is prepared as an active ingredient of a composition for administration, and the claims merely recites a whitening agent, an immunofunction controlling agent, an appetite controlling agent or a cosmetic preparation comprising the peptide of formula (I) as active ingredient, therefore, claims 4, 8-11 and 16-19 are anticipated by the reference.

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In response, applicants indicate Examiner has mistakenly named the compound of Example 21 as containing naphthyl instead of naphthoyl, and Saika *et al* disclose a virtually never ending genus of compound and fails to disclose with sufficient specificity any compound falling within the scope of the claimed invention. The response has been fully considered, however, the argument is not found persuasive because the compound of N-(2-naphthoyl)-N-methyl-D-phenylalanyl-L-tryptophan meets the structural criteria of the claimed peptide as indicated in the paragraph above (when n is 0, 2-naphthyl-C(=O) is 2-naphthoyl). It is not Examiner's intention to name the compound with 2-naphthyl rather a typographic error.

Conclusion

12. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

April 10, 2004

Christopher S. F. Low
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